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K962157
Physiometrix, Inc.
510(k), Premarket Notification
NeuroLink NeuroMonitoring System, Model 1310

SUMMARY OF SAFETY AND EFFECTIVENESS

Date: June 3, 1996

Company: Physiometrix, Inc.
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Subject Device: Model 1310, NeuroLink NeuroMonitoring System

Predicate Device: K930080, HydroDot NeuroMonitoring System

Classification: Class II, CFR 21 Part 882.1320, Cutaneous Electrodes
Class II, 21 CFR Part 882.1835, Physiological Signal Amplifier

Description: The e-Net NeuroMonitoring System consists of a set of components that work together to acquire and present EEG signal to any existing EEG recording and analysis equipment. The components in the original submission included Biosensor electrodes, e-Net headpiece, Patient Module, fiber optic interface, Monitor Module, AC power supply, and EEG Adapter Cable. The components of this submission include Biosensor electrodes, e-Net headpiece, Patient Module, fiber optic interface, and DSP Interface Card (replaces Monitor Module). The AC power supply and EEG Adapter Cable have been eliminated.

The modified system discussed in this submission uses the same electrodes and headpiece for signal acquisition but has changes in the modules used to transmit signals to the existing EEG recording and analysis equipment.

The Patient Module is a small battery powered unit attached to the patient. Power is enabled when the Patient Module is plugged into the DSP Card via the fiber optic cable, the host digital EEG computer is in the powered state and the Patient Module is enabled by pressing the control button located on the Patient Module. A five meter fiber optic cable is standard. The fiber optic cable provides outstanding patient isolation and flexible patient EEG Record Station placement options. A connector located at the top end of the module attaches to our standard e-Net headpiece or optionally a mini-jack for interface to standard cup electrodes. Self test, calibration and impedance tests are

remotely activated from the host Digital EEG Machine through the DSP Interface Card or locally by depressing the appropriate test button on the Patient Module. A visual indication of control button function, system status and out of range impedance can be provided on the LCD display as controlled from the host Digital EEG Machine.

Intended Use:

The NeuroLink NeuroMonitoring System has the same intended use as the predicate device, the HydroDot NeuroMonitoring System. Both are designed to locate EEG electrodes according the 10-20 International System and present electrical signal sensed by the electrodes from the skin to existing EEG recording, analysis and archiving equipment.